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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,582	04/21/2004	Jose Aquino	03-169-A	5274
20306 7590 06/22/2007 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 06/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,582

Applicant(s)

AQUINO ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election of Group I, claims 1-12 reading on the species disclosed on page 74, first compound in the reply filed on Feb. 12, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Based on the species of election, claim 9 and claims 1-8, 12 and composition thereof, claim 17, reading on one of X₁, X₂, X₃ is SO₂ and the remaining are CH₂, i.e. compounds with an isothiochromene core, is examined. Claims 10-11, 13-16 and the remaining subject matter of claims 1-8, 12 which have distinct cores, are withdrawn from consideration per 37 CFR 1.142(b).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12, 17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by John et al. US 7,176,242 supplemented with CA 138:385173.

The structure of the disclosed compounds in US 7,176,242 is delineated by CA 138, see RN 527732-56-5 anticipated the instant elected species, thus, claims reading on the species, see also RN 527732-60-1 which anticipated the other scope of the claims.

The issued patent US 7,176,242 which is commonly assigned has a different inventive entity which disclosed the anticipatory compounds. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. Applicants are requested to state under oath that whether the disclosed anticipatory

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compounds were claimed in any continuation applications and follow the procedure of MPEP §715.01 (b)-(c) in clarification of the issue. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 12, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al. US 7,176, 242, supplemented with CA 138:385173.

Determination of the scope and content of the prior art (MPEP §2141.01)

John et al. '242 disclosed anticipatory compounds as delineated supra. Variation of the anticipatory compounds guided by the teaching of the generic disclosure by John et al. '242, other species such as RN 527732-58-7, RN 527732-59-8, RN 527732-61-2, or RN 527732-62-3 were also explicitly disclosed and enabled.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the elected species and broadly disclosed prior art compounds such as RN 527732-58-7, RN 527732-59-8, RN 527732-61-2, or RN 527732-62-3, is that instead of m=1-3, the prior art compounds have m=0. Generically, John et al. '242 taught that m=0 or m=1 compounds are optional choices for such inhibitors of beta-secretase.

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Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the John. et al. '242 is in position of the instant claims **because** not only John et al. '242 generically taught the concept of the claimed compounds, the explicit example would have guided one having ordinary skill to make and choose the instantly claimed compounds with variations of B with the breadth of the instant scope i.e. heterocycle, beyond the species of imidazolyl or phenyl. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

4. Claims 1-9, 12, 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 13 of U.S. Patent No. 7,223,774 alone or in view of John et al. US 7,176,242.

Determination of the scope and content of the prior art (MPEP §2141.01)

The issued claims of US 7,224,774 are drawn to Z is aryl, heteroaryl or heterocyclo compounds, i.e. m=0 compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is that the instant claims have one methylene insertion i.e. m=1 vs. m=0 of the issued claims. The issued patent John et al. '242 (supplemented by structural delineation from CA 138) taught that the Z moiety being aryl, heteroaryl, heterocycle or arylmethyl, heteroarylmethyl etc. are optional choices for such compounds (see explanation supra in section 3 hereby incorporated by reference).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of US 7,223,774 alone or together with US 7,176,242 would find the instant claims and the issued claims prima facie because the one methylene addition is a conventionally recognized modification to obtain more compounds with similar biological activity (In re Wood 199 USPQ 131, In re _____) especially, the prior art by John et al. '242 provided guidelines that such modification is enabled and operable. The modification of a known compound with attributes of another known compound is prima facie obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-9, 12, 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending SN 11/090,520 in view of John et al. US 7,176,242 and King et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

The copending claims are drawn to compounds of the instant formula I wherein the Z moiety is alkyl and the OH moiety is SH or NH₂.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is that the instant claims have substituted alkyl i.e. benzyl, and the bioisostere OH instead of SH or NH₂. The issued patent John et al. '242 (supplemented by structural delineation from CA 138) taught that the Z moiety being alkyl (see RN 527732-66-7 or 527733-12-6) or benzyl (see RN 527732-60-1) are optional choices for such compounds. King taught that bioisosteres are conventional structural modification in medicinal chemistry to obtain more compounds with similar activity.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the modification and expectation of such modification in the possession of one having ordinary skill in the beta-secretase compound art. One motivated by obtaining more compounds having similar activity for best pharmaceuticals would be suggested by the above references to carry out such feature in bioisosteric replacement or optional structural replacement with known attributes in prior art proven compounds. The modification of one proven compounds with attributes of other proven compounds is prima facie obvious.

This is a provisional rejection since the copending application was not issued. Applicants are urged to show clear demarcation beyond obviousness double patenting between the instant claims and the copending claims or file a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jun. 14, 2007


Celia Chang
Primary Examiner
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